K121876

5. 510(k) summary

OCT 19 2012

Preparation date: June 22, 2012

Submitter:
aap Biomaterials GmbH
Lagerstraße 11-15
64807 Dieburg
Germany
Phone: +49 6071 / 929-0
Fax: +49 6071 / 929-100

Contact person: Volker Stirnal

Trade name: Vertecem II Mixing Kit

Common name: PMMA Bone Cement (For Vertebroplasty)

Classification: Polymethylmethacrylate (PMMA) Bone Cement
21 CFR 888.3027, Class II

Product Code: LOD, NDN

Panel: Orthopedics

Predicate device to which substantial equivalence is claimed:

Manufaturer	Device Name	510(k) #
Teknimed S.A.S.	Vertecem	(K090435)

Manufaturer	Device Name	510(k) #
aap Biomaterials	BonOs Inject	(K090460)

K121876

Device description:

Vertecem II is a radio-opaque, injectable acrylic bone cement used for the treatment of pathological fractures of the vertebral body using a Vertebroplasty or Kyphoplasty procedure.
The Vertecem II Mixing Kit consists of sterile packed components. When the cement components are mixed together, they become a self hardening, radio-opaque bone cement.

Scientific concepts, significant physical and performance characteristics:

Bone cements in general are self-polymerizing two-component systems comprising a powder and a liquid which polymerize at room temperature immediately after they are mixed together.

The major powder component is polymethyl methacrylate / acrylate. Furthermore a radio-opacifier and benzoyl peroxide as initiator is included.
The liquid mainly consists of methyl methacrylate. It is furthermore comprised of an activator and a stabilizer to prevent premature polymerization.

When the powder and liquid components are mixed together, the activator DmpT, contained in the liquid activates the initiator in the powder component. This reaction starts the polymerization of the MMA, which is bonded with the polymer powder during ongoing polymerization. A description of polymerization technology is depictured in section 10- Executive summary, annex 10 – D.

As a result, a viscous injectable paste is obtained which can be introduced into a vertebral body using a suitable application system. Heat is generated during setting as a result of the progressive polymerization and exothermic reaction respectively. After curing the bone cement is able to stabilize the vertebral lesions and vertebral compression fractures. The setting or curing time is greatly influenced by the temperature of the components and environment, which is common for all acrylic bone cements.

Statement of the intended use:

The Vertecem II Bone Cement is used for the fixation of pathological fractures of the vertebral body using Vertebroplasty or Kyphoplasty procedures. Painful vertebral compression fractures of the vertebral body may result from osteoporosis, benign lesions (hemangioma), or malignant lesions (metastatic cancers, myeloma).

K121876

Summary of technological characteristics of the new device in comparison to the predicate devices:

Vertecem II bone cement comprises the same materials, mechanical safety and performance as the legally marketed devices BonOs Inject and Vertecem.

Trade Name	**Vertecem II Mixing Kit**	**Vertecem**	**BonOs Inject**
Common name	PMMA Bone Cement	PMMA Bone Cement	PMMA Bone Cement
Responsible manufacturer	aap Biomaterials	Teknimed S.A.S.	aap Biomaterials
510(k) Number	-	K090435	K090460
Device Classification Name	Cement, Bone, Vertebroplasty	Cement, Bone, Vertebroplasty	Cement, Bone, Vertebroplasty
Product Code	NDN	NDN	NDN
Classification	Class II	Class II	Class II
Regulation no.	21 CFR 888.3027	21 CFR 888.3027	21 CFR 888.3027

The effectiveness and substantial equivalence of Vertecem II Bone Cement was determined by physical, chemical and mechanical comparative tests to Vertecem and BonOs Inject by comparing the results of the relevant data.

In summary, Vertecem II Bone Cement is as safe and effective for the declared indications as the predicate devices BonOs Inject and Vertecem.

In conclusion substantially equivalence has been demonstrated for Vertecem II Mixing Kit in comparison to Vertecem (K090435) and BonOs Inject (K090460).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

aap Biomaterials GmbH
% Mr. Volker Stirnal
Director, Quality Assurance and Regulatory Affairs
Lagerstrasse 11-15
Dieburg, Germany D-64807

OCT 19 2012

Re: K121876
Trade/Device Name: Vertecem II Mixing Kit
Regulation Number: 21 CFR 888.3027
Regulation Name: Polymethylmethacrylate (PMMA) bone cement
Regulatory Class: Class II
Product Code: MDN, LOD
Dated: October 15, 2012
Received: October 16, 2012

Dear Mr. Stirnal:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4. Indications for Use

510(k) Number:

Device Name: Vertecem II Mixing Kit

Indications for Use:

The Vertecem II Bone Cement is used for the fixation of pathological fractures of the vertebral body using Vertebroplasty or Kyphoplasty procedures. Painful vertebral compression fractures of the vertebral body may result from osteoporosis, benign lesions (hemangioma), or malignant lesions (metastatic cancers, myeloma).

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K121876

Prescription Use ____X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)